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12 **UNITED STATES DISTRICT COURT**
13 **NORTHERN DISTRICT OF CALIFORNIA**
14 **SAN JOSE DIVISION**
15

16 THERANOS, INC. and ELIZABETH HOLMES,

17 Plaintiffs,

18 v.

19 FUISZ PHARMA LLC, RICHARD C. FUISZ,
20 and JOSEPH M. FUISZ,

21 Defendants.
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Case No. 11-CV-05236-PSG

**NOTICE OF MOTION AND MOTION TO
AMEND INVALIDITY CONTENTIONS**

Dept.: Courtroom 5, 4th Floor
Judge: Honorable Paul Singh Grewal

Hearing: September 24, 2013

Trial: November 18, 2013

NOTICE OF MOTION AND MOTION**TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

NOTICE IS HEREBY GIVEN that on September 24, 2013, at 10 a.m., or as soon thereafter as counsel may be heard in Courtroom 5 of the above entitled court, located at 280 South First Street, San Jose, California, Plaintiffs Theranos, Inc. and Elizabeth Holmes (collectively, “Theranos”) will and hereby do move the Court for an order granting leaving to amend Theranos’s initial invalidity contentions.

This motion is based on this Notice of Motion and Motion, the following Memorandum of Points and Authorities, the supporting Declaration of Michael Jay, the pleadings and papers on file with the Court in this action, any matters on which the Court may take judicial notice, any evidence or argument presented at the hearing on this motion, and any other matters the Court deems proper.

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SANTA MONICA, CALIFORNIA

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Pursuant to Patent Local Rule 3-6, Theranos, Inc. and Elizabeth Holmes (collectively, “Theranos”) move to supplement their invalidity contentions to reference three material prior art references that Theranos recently discovered but that have been in the Defendants’ possession from before this litigation began. Out of an abundance of caution, Theranos additionally seeks to amend its contentions to make clear that a different prior art reference that it originally cited in relation to four dependent claims (Claims 3, 10, 13, and 15) applies with equal force to independent Claims 1 and 9, which the dependent claims incorporate by reference. Because Theranos acted diligently and the Defendants face no prejudice, Theranos respectfully requests that its motion be granted in its entirety.

II. BACKGROUND

The Court’s March 18, 2013, Case Management Order specified a fact discovery cutoff date of June 7, 2013. As the cutoff date approached, the parties met and conferred to finalize deposition dates and locations for various witnesses. With one exception, the parties agreed to depose most witnesses either before or within a few days after the cutoff date. The exception was Alan Schiavelli of Antonelli, Terry, Stout & Kraus LLP (“Mr. Schiavelli’s law firm”), who performed patent prosecution services for defendants. At Mr. Schiavelli’s request, the parties agreed to depose him on June 27, 2013. (Declaration of Michael Jay in Support of Plaintiffs’ Motion to Amend Invalidity Contentions (“Jay Decl.”) Ex. 1.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Theranos immediately began to investigate the issue.

1 Theranos subsequently discovered that the JPO had rejected the Japanese Application because
2 it was anticipated by at least three pieces of prior art that Theranos had never seen: (1) Siddiqui, et
3 al., “System for Monitoring Physiological Characteristics,” PCT No. WO 2005/065538 A2, published
4 July 21, 2005 (“Siddiqui”); (2) Watanabe, et al., “Dosage Determination Supporting Device, Injector,
5 and Health Management Supporting System,” Japanese Laid-Open Publication No. 2004-555
6 (corresponding to European Patent Application EP 1 498 067 A1, published January 19, 2005)
7 (“Watanabe”); and (3) Wakatake, “Automatic Analyzer for Feces Occult Blood,” Japanese Laid-
8 Open Publication No. 08-035969, published June 2, 1996 (“Wakatake”) (collectively, the “Japanese
9 Art”). (Jay Decl. Ex. 4–6.) Although Siddiqui and Watanabe had English-language counterparts that
10 Theranos was able to locate after some investigation, Wakatake was available only in Japanese.
11 Theranos immediately arranged for a certified translation of Wakatake so that Theranos and its
12 counsel could analyze it. This translation was not ready to be reviewed until July 24, 2013.

13 In contrast, the Defendants and Mr. Schiavelli had been well aware of the Japanese Art for
14 years. [REDACTED]

15 [REDACTED] The JPO informed Defendants
16 of its reasons for refusing the Japanese Application on March 22, 2011 (Jay Decl. Exs. 8, 9.) Thus,
17 the Defendants were well aware of the Japanese Art identified by the JPO more than seven months
18 before Theranos filed this case and the Defendants filed their now-dismissed patent infringement case
19 against Theranos.

20 On August 13, 2012, Theranos served a set of document requests on the Defendants,
21 including, *inter alia*, “documents that refer or relate to the ’612 Patent, including any provisionals or
22 patent applications relating to the ’612 patent, and the prosecution thereof.” (Jay Decl. Ex. 12 at 6.)
23 Two days later, Theranos subpoenaed Mr. Schiavelli’s law firm for, *inter alia*, documents
24 “concerning the ’612 Patent, including the prosecution thereof, such as, without limitation, any prior
25 art evaluated, analyzed, or otherwise considered by you.” (Jay Decl. Ex. 13 at 4.) Mr. Schiavelli’s
26 law firm and the Defendants raised limited objections to these requests, but they did not take the
27 position in their written objections and responses that they would not produce responsive prior art,
28 and Theranos never agreed that Defendants could withhold any relevant prior art references.

1 Nevertheless, neither Mr. Schiavelli's law firm nor Defendants produced the Japanese Art.

2 Theranos's initial invalidity contentions did reference a different prior art reference: Heidt et
3 al., U.S. Patent No. 5,089,229, "Chemical Analyzer," which issued on February 18, 1992 ("Heidt").
4 (See Jay Decl. Ex. 7.) Heidt teaches the chemical analysis of biological fluids, including "a chemical
5 analyzer in which test results are analyzed according to species and out of normal bounds are
6 flagged." (Jay Decl. Ex. 7 at 1:15–17; 2:65–68.) Heidt further states that, "[i]f the test results are
7 outside the normal ranges expected, the analyzer will alert the user to that fact and will provide the
8 user with a possible diagnosis of the ailment." (Jay Decl. Ex. 7 at 34:65–35:1.) Theranos's initial
9 invalidity contentions cited Heidt against all of dependent claims in the '612 Patent that reference
10 "the display" and bar codes, including Claims 3, 10, 13, and 15. Theranos's initial invalidity
11 contentions did not duplicate its reference to Heidt for independent Claim 1—which is incorporated
12 into Claim 3 by reference—or independent Claim 9, which is incorporated into Claims 10, 13, and 15
13 by reference.

14 **III. DISCUSSION**

15 Patent Local Rule 3-6 permits a party to petition the Court for an order to amend its invalidity
16 contentions upon a timely showing of good cause. N.D. Cal. Patent L.R. 3-6. The rule expressly
17 recognizes that, absent undue prejudice to the non-moving party, the "[r]ecent discovery of material,
18 prior art despite earlier diligent search" supports a finding of good cause. *Id.* To show good cause, a
19 party seeking to amend its infringement contentions ordinarily must show that it "acted with
20 diligence in promptly moving to amend when new evidence is revealed in discovery." *O2 Micro Int'l*
21 *Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006). "Nevertheless, even if the
22 movant was arguably not diligent, the court may still grant leave to amend." *OpenDNS, Inc. v. Select*
23 *Notifications Media, LLC*, No. C11-05101 EJD (HRL), 2013 WL 2422623 at *2 (N.D. Cal. June 3,
24 2013). "The court then considers whether there will be undue prejudice to the non-moving party."
25 *Id.*

26 Here, Theranos acted diligently in investigating the prior art and amending its claims, and
27 Defendants face no prejudice from these amendments. Thus, Theranos respectfully requests that the
28 Court grant Theranos leave to amend its invalidity contentions. As shown in more detail in the

1 accompanying claim charts, the references discussed below, alone or in combination with each other
2 or with the art Theranos previously cited in its Patent Local Rule 3-3 Invalidity Contentions, render
3 obvious each claim of the '612 Patent. In addition, the Watanabe reference anticipates Claims 1, 7, 8,
4 9, 13, 17, and 18 of the '612 Patent.

5 **A. Good Cause Exists to Permit Amendment in Relation to the Japanese Prior Art**

6 **1. Theranos Acted Diligently**

7 *First*, Theranos acted diligently in preparing its initial invalidity contentions. Theranos's
8 counsel conservatively estimate that Theranos employees, its consultants, and its outside counsel
9 spent hundreds of hours reviewing prior art and preparing Theranos's invalidity contentions in
10 relation to this litigation. (Jay Decl. ¶ 2.) No one involved in the preparation of those contentions
11 was aware of the Japanese Art.

12 *Second*, Theranos did not know of the Japanese Art sooner because Defendants and Mr.
13 Schiavelli's law firm never produced the art, even though it was in their possession and responsive to
14 Theranos's document subpoenas and requests. Theranos's August 13, 2012 document request
15 requested the production of "documents that refer or relate to the '612 Patent, including any
16 provisionals or patent applications relating to the '612 patent, and the prosecution thereof." (Jay
17 Decl. Ex. 12 at 6.) [REDACTED]

18 [REDACTED] Because the Japanese Art
19 cited by the JPO in rejecting the [REDACTED] counterpart to the '612 Patent calls into question the
20 validity of Defendants' '612 Patent, it is unambiguously responsive to the document request served
21 on Defendants and should have been produced.

22 Likewise, on August 15, 2012, Theranos subpoenaed Mr. Schiavelli's law firm for documents
23 "concerning the '612 Patent, including the prosecution thereof, such as, without limitation, any prior
24 art evaluated, analyzed, or otherwise considered by you." (Jay Decl. Ex. 13 at 4.) [REDACTED]

25 [REDACTED]
26 [REDACTED] Because it was the basis for the JPO's rejection of
27 defendants' application, Mr. Schiavelli's law firm necessarily would have been "evaluating,
28 analyzing, or otherwise considering" the Japanese Art as part of that appeal. Similarly, because

invalidity is a common defense to a patent infringement case, Mr. Schiavelli's law firm and the Defendants were required to evaluate the Japanese Art and its impact on the asserted originality of the claims in the '612 Patent as part of their Rule 11 obligations before bringing their infringement claims against Theranos in Delaware—and again when they answered Theranos's invalidity claims in response in Theranos's amended complaint. *See* Fed. R. Civ. P. 11(b). Nonetheless, neither the Defendants nor Mr. Schiavelli's law firm produced the Japanese Art in response to Theranos's discovery request or subpoena. Instead, Mr. Schiavelli did not even allude to the possible existence of the Japanese Art until weeks after fact discovery closed.

The Defendants contend that they and Mr. Schiavelli's law firm were justified in not producing the Japanese prior art because the parties allegedly agreed orally that "foreign prosecution documents from the Antonelli law firm" were not "the documents that [Theranos] sought" in its document subpoena to Mr. Schiavelli's law firm. (*See* Jay Decl. Ex. 14.) Whatever the Defendants contend is the scope of any discovery agreement concerning "foreign prosecution documents," Theranos certainly did not agree that the Defendants could withhold any material prior art references.

Third, Theranos promptly acted to amend its invalidity contentions. Theranos learned of the potential existence of the invalidating art on June 27, 2013. Since then, Theranos (1) located and translated the documentation regarding Defendants' prosecution of the counterpart to the '612 Patent in the JPO; (2) reviewed the correspondence between the JPO and Defendants, and identified the three prior art references that the JPO used to reject the Japanese counterpart application as unpatentable; (3) located and reviewed English-language counterparts to two of those pieces of art, Siddiqui and Watanabe; (4) obtained and reviewed a certified translation of the final piece of art, Wakatake, which was available only in Japanese; and (4) reviewed and amended Theranos's initial invalidity contentions in light of this art. Theranos clearly "acted with diligence in promptly moving to amend when new evidence is revealed in discovery." *O2 Micro Int'l Ltd.*, 467 F.3d at 1363.

2. Granting Leave to Amend Would Not Cause Undue Prejudice.

Amendment to the invalidity contentions would not cause undue prejudice to the Defendants.

This is not a situation where a party has delayed revising invalidity conventions to gain a tactical advantage over the other party; quite the opposite. Indeed, while the existence of the

Japanese art was recent news to Theranos, Defendants have known about the Japanese Art for over two years. Specifically, the JPO advised the Defendants of its reasons for refusing the Japanese Application on March 22, 2011. (Jay Decl. Exs. 8, 9.) Thus, the Defendants and Mr. Schiavelli knew of the Japanese Art identified by the JPO more than seven months before Theranos filed this lawsuit and Defendants brought their now-dismissed patent infringement case against Theranos. Further, the Defendants and Mr. Schiavelli not only knew that the Japanese Art existed; they also knew that it was directly relevant to Theranos's invalidity claims. Their failure to produce the art is inexcusable.

Furthermore, the Defendants and Mr. Schiavelli necessarily evaluated this prior art on numerous occasions, including: (1) when they were first notified of the JPO's decision to reject their patent application; (2) when preparing their appeal of the JPO's decision; (3) when working on other foreign patent applications related to the '612 Patent; (4) when considering whether to file patent infringement claims against Theranos in Delaware; and (5) when preparing a response to Theranos's patent-infringement claims in its amended complaint in California. Indeed, the Defendants must have already analyzed the Japanese Art and formulated their validity arguments—however weak—before Theranos filed its original invalidity contentions in this case.

Under such circumstances, the Defendants cannot identify *any* prejudice that would result if Theranos is permitted to amend its original invalidity contentions.

B. Good Cause Exists to Permit Amendment in Relation to Heidt

Good cause also exists for Theranos to supplement its invalidity contentions on Claims 1 and 9 to more explicitly include references to prior art already referenced in its contentions for four dependent claims, each of which incorporates either Claim 1 or Claim 9 by reference. In this regard, if the amendment will not cause undue prejudice, a court may grant leave to amend invalidity contentions even if the movant arguably was not diligent. *OpenDNS, Inc.*, 2013 WL 2422623 at *2 (citing *Board of Trs. Of Leland Stanford Junior Univ. v. Roche Molecular Sys.*, No. C-05-04158-MHP, 2008 WL 624771 at *2 (N.D. Cal. Mar. 4, 2008)).

Heidt relates to the chemical analysis of biological fluids and envisions “a chemical analyzer in which test results are analyzed according to species and out of normal bounds are flagged.” (Jay

Decl. Ex. 7 at 1:15–17; 2:65–68.) Heidt specifies that, “[i]f the test results are outside the normal ranges expected, the analyzer will alert the user to that fact and will provide the user with a possible diagnosis of the ailment.” (Jay Decl. Ex. 7 at 34:65–35:1.)

Theranos’s original invalidity contentions already reference Heidt in relation to four dependent claims. Theranos cited Heidt against Claims 3, 10, 13, and 15 of the ’612 Patent in its original invalidity contentions. All of those claims incorporate either Claim 1 or Claim 9 by reference. Specifically, Claim 3 incorporates Claim 1 (as part of Claim 2), while Claims 10, 13, and 15 each incorporate Claim 9. Defendants clearly had ample notice that Theranos viewed Heidt as an invalidating reference. Moreover, the PTO Examiner applied Heidt against the ’612 Patent in one of its initial rejections of Defendants’ application many years ago. On August 20, 2008, the Examiner explained that Heidt “discloses that the computer of the analyzer allows for setting values that relate to ‘normal values’ for various analytes” and that “if an analysis falls out of the normal range set for the analyte and analyses being done for such, an indication/alert is provided to the display”. (Jay Decl. Ex. 11 at 055.) And on February 20, 2009, the Defendants, through Mr. Schiavelli’s law firm, responded to the Examiner and acknowledged that Heidt disclosed the following: “The computer of the analyzer itself has stored in memory the normal ranges for tests which are performed with respect to each category of animal.” (Jay Decl. Ex. 12 at 087–088.)

In short, Theranos wishes to amend its invalidity contentions to clarify only what Defendants already know. The Defendants have known about the Heidt art for nearly five years. [REDACTED]

[REDACTED] There is therefore no prejudice in permitting Theranos to formally amend its invalidity contentions to conform to the prior understanding and admissions of the named inventor.

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IV. CONCLUSION

Good cause having been shown, Theranos respectfully moves the court for leave to amend its invalidity contentions.

Dated: August 9, 2013

BOIES, SCHILLER & FLEXNER LLP

By: /s/ Michael D. Jay
Michael D. Jay

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8 **UNITED STATES DISTRICT COURT**
9 **NORTHERN DISTRICT OF CALIFORNIA**
10 **SAN JOSE DIVISION**
11

12 THERANOS, INC. and ELIZABETH HOLMES,

13 Plaintiffs,

14 v.

15 FUISZ PHARMA LLC, RICHARD C. FUISZ,
16 and JOSEPH M. FUISZ,

17 Defendants.
18
19

Case No. 11-CV-05236-PSG

**[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION TO AMEND
INVALIDITY CONTENTIONS**

Dept.: Courtroom 5, 4th Floor
Judge: Honorable Paul Singh Grewal

TRIAL DATE: NOVEMBER 18, 2013

[PROPOSED] ORDER

Before the Court is the Plaintiffs' Motion to Amend Invalidity Contentions and Supporting Declaration. For the reasons stated in that motion, the accompanying Memorandum of Points and Authorities, the supporting Declaration of Meredith Dearborn, the pleadings and papers on file with the Court in this action, and any other matter that the Court deems just and proper, the Court hereby **GRANTS** the motion.

IT IS SO ORDERED.

Dated: _____, 2013

HONORABLE PAUL SINGH GREWAL
United States Magistrate Judge